REMARKS

In the Office Action of 19 August 2009, claims 1-8 and 10-16 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failure to point out and distinctly claim the subject matter of the invention. Claims 1-5, 10, 11, 14 and 16 were rejected under 35 U.S.C. § 102(e), as anticipated by U.S. Patent No. 6,626,935 to Ainsworth et al. (hereinafter "Ainsworth"). Claims 6- 8 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Ainsworth in view of U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu"). Also under 35 U.S.C. § 103(a), claims 12, 13, and 15 were rejected as being unpatentable over Ainsworth in view of U.S. Pat. No. 6,423,090 to Hancock (hereinafter "Hancock"). Claims 1, 11 and 16 are amended herein. No claims are cancelled or added.

Claim 1 has been amended to specify that it is the hinge axis which extends transversely with respect to the bearing structure and to eliminate reference to "the stent" in favor of "the bearing structure" consistent with the remainder of the claim. Additionally, while only one "expansion direction" is recited in claim 1, the claim has also been amended to further recite that the expansion direction is the expansion direction of the bearing structure as provided in paragraphs 0058-0060. Furthermore, claims 11 and 16 have been amended to recite, "…wherein the cuts are expanded in end regions of the cuts to reduce a notch effect." Support for the amendments to claims 11 and 16 may be found in the specification at paragraph 0065 and Fig. 1a, as well as paragraph 0069 and Fig 4a. Therefore, claims 1-8 and 10-16 satisfy the requirements under 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection of these claims under 35 U.S.C. § 112, second paragraph is respectfully requested.

Ainsworth was considered to anticipate claims 1-5, 10, 11, 14, and 16. Ainsworth's "springs 36" were considered to constitute spring struts as recited in the claims, while "ring undulations 38" were considered to constitute hinge struts. However, the mechanism of Aisworth is entirely different from that of the present invention. Ainsworth repeatedly provides that the prior design is intended to provide flexibility during insertion in order to conform to the contours of the patient's blood vessels. (See, for example, column 3, lines 31-39 and column 4, lines 40-42). Accordingly, the transition of Ainsworth's stent from an unexpanded to an expanded condition is also entirely different. Ainsworth describes the expansion as one in which the "subpeaks and valleys[,] substantially retain their original shape so as to provide flexibility in the stent after implantation." (Column 6, lines 1-3). While Ainsworth does provide, "During expansion of the stent, the respective one end or the other of the undulating portion of the rings may tip outwardly to extend radially outwardly from the exterior cylindrical outline defined by the expanded stent" (column 5, lines 27-31), this does not approach the mechanism of expansion of the presently claimed structure.

A significant difference between Ainsworth's stent and the claimed invention is the feature described in claim 1 as follows:

> …wherein the spring struts and the hinge struts are of such a configuration and arrangement that the bearing structure is capable of going from a compressed condition to a transitional condition, to an expanded condition, and wherein in the compressed state, the spring strut and hinge strut bear closely against each other and are separated by cuts, and the central axis of the hinge strut is transverse to the reference axis, and
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> wherein in the transitional condition, the hinge strut is pivoted at the hinge axis in an expansion direction such that the central axis of the hinge strut is approximately parallel to the reference axis and the spring struts rotate in a first direction such that the spring struts are initially resiliently deflected transversely to the expansion direction of the bearing structure, and
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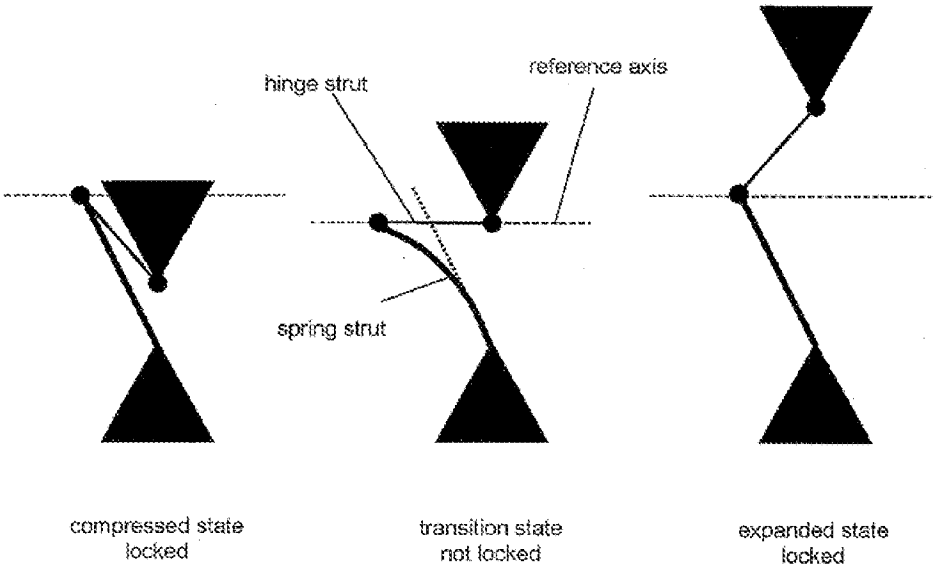
> wherein in the expanded condition, the hinge strut additionally pivots at the hinge axis in the expansion direction of the bearing structure beyond the reference

> axis such that the central axis of the hinge strut is transverse to the reference axis and the spring struts rotate in a second direction opposite to the first direction, thereby providing that both the compressed condition of the bearing structure and also the expanded condition of the bearing structure are stabilized by a spring action emanating from the spring struts.

The recited behavior of the spring strut and the hinge strut is illustrated in Fig. 2 of the application. It may also be helpful to refer to a simplified schematic drawing of the recited mechanism of action, as provided in the illustration below. While the illustration only provides the motion of the hinge strut and spring strut in two dimensions, this simplified illustration may show certain aspects of the mechanism more clearly.

In the illustration, the reference axis is indicated, while the hinge axis forms "at the juncture of the spring strut and the hinge strut" and extends "transversely with respect to the bearing structure." In other words, in the illustration, the hinge axis is perpendicular to the plane of the page. The expansion direction of the structure is toward the top of the page.



Starting in the compressed state (left schematic), "the spring strut and hinge strut bear closely against each other and are separated by cuts, and the central axis of the hinge strut is transverse to the reference axis."

As the structure expands, it proceeds through a transition state (middle schematic), in which "the hinge strut is pivoted at the hinge axis *(that is, at the juncture of the spring strut and the hinge strut)* in an expansion direction of the bearing structure *(toward the top of the page)* such that the central axis of the hinge strut is approximately parallel to the reference axis *(as shown)* and the spring struts rotate in a first direction such that the spring struts are initially resiliently deflected transversely to the expansion direction of the bearing structure *(note the deflection of the spring strut relative to its position in the compressed state, noted by the dashed line)*."

Finally, the structure achieves an expanded state (right schematic), and "the hinge strut additionally pivots at the hinge axis *(at the juncture of the spring strut and the hinge strut)* in the expansion direction of the bearing structure *(toward the top of the page)* beyond the reference axis such that the central axis of the hinge strut is transverse to the reference axis *(as shown)* and the spring struts rotate in a second direction opposite to the first direction *(i.e., back toward their original position in the compressed state).* This mechanism of action provides "that both the compressed condition of the bearing structure and also the expanded condition of the bearing structure are stabilized by a spring action emanating from the spring struts."

No teaching or suggestion is observed in Ainsworth of such a mechanism. At most, Ainsworth provides "During expansion of the stent, the respective one end or the other of the undulating portion of the rings may tip outwardly to extend radially outwardly from the

exterior cylindrical outline defined by the expanded stent, when in its unflexed condition to thus slightly radially embed in the wall of the vessel and help secure the expanded stent in its implanted location." (Column 5, lines 27-35). Therefore, at best Ainsworth only provides for a deflection of a portion of a stent outward in the expanded state (to "help secure the expanded stent in its implanted location") and does not provide the type of mechanism as claimed, with deflection of the spring strut in the transitional state. Ainsworth provides no teaching or suggestion of a stent such as the claimed structure in which, in the expanded state, the structure is prevented from flexing back into its initial compressed geometry by the spring action emanating from the spring struts in the transitional state, that is, when the hinge strut is essentially parallel to the reference axis.

In the Office Action, the following annotated figure of Ainsworth was also provided:

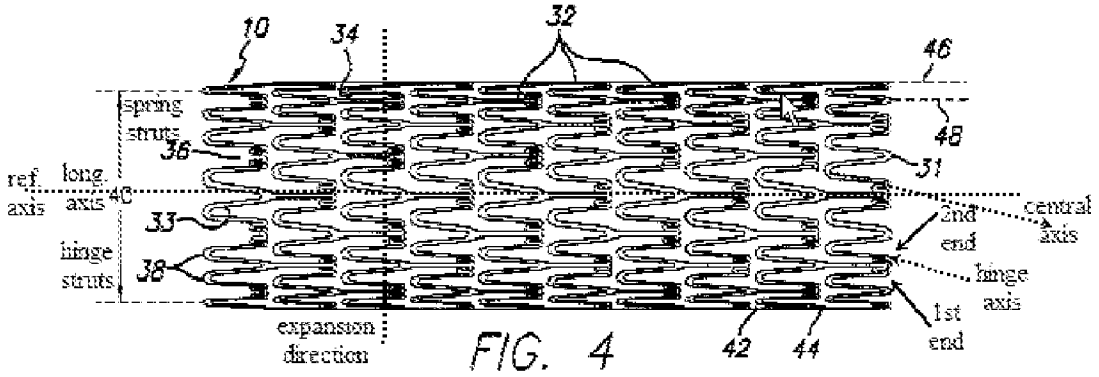


FIG. 4

It was alleged in the Office Action that, "in the transitional condition the hinge strut is pivoted about the hinge axis in an expansion direction such that the central axis of the hinge strut is parallel to the reference axis when the hinge strut begins to expand in the radial direction through decrease in the waveform's amplitude and frequency…" However, it is clear from this annotated Figurethat as Ainsworth's stent expands, the angle formed by the central axis of the hinge strut and the reference axis must increase, not decrease. Stated differently, for the

reference axis and the central axis of the hinge strut to be parallel, the prior stent must be compressed, not expanded.

Therefore, Ainsworth does not teach or suggest all the elements of claim 1, and claim 1 patentably distinguishes over Ainsworth. Likewise, claims 2-5, 10, 11, 14 and 16, which depend from and include all the limitations of claim 1, also patentably distinguish over Ainsworth. Withdrawal of the rejection of these claims under 35 U.S.C. § 102(e) is respectfully requested.

Claims 6-8 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Ainsworth in view of Wu. Wu is relied upon for the teaching of the use of a magnesium alloy or a bioresorbable material. However, as with Ainsworth, discussed above, Wu also provides no teaching or suggestion of the movement of the various components relative to each other, particularly the rotation of spring struts when passing from the compressed condition to the transitional condition to the expanded condition. Therefore, neither Ainsworth nor Wu teach or suggest all of the limitations of claims 6-8, and these claims patentably distinguish over the Ainsworth in view of Wu. Withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 12, 13 and 15 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Ainsworth in view of Hancock. Hancock is relied upon for the teaching of a stent having a ring with curvilinear struts having a large cross sectional area in one region that tapers to a smaller cross sectional area in another region, where the transitional region is formed at a juncture within the curvilinear ring. However, as with Ainsworth, discussed above, Hancock also provides no teaching or suggestion of the movement of the various components relative to

each other, particularly the rotation of spring struts when passing from the compressed condition to the transitional condition to the expanded condition. Therefore, neither Ainsworth nor Hancock teach or suggest all of the limitations of claims 12, 13 or 15, and these claims patentably distinguish over the Ainsworth in view of Hancock. Withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

Therefore, it is respectfully maintained that the claims patentably distinguish over all of the cited references. The issuance of a Notice of Allowance is earnestly solicited.

The outstanding Office action was mailed on 19 August 2009. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, this response is timely filed on November 19, 2009 and no petition for an extension of time is believed to be due. Nevertheless, the Applicant hereby makes a conditional petition for an extension of time for response in the event that such a petition is required and has been overlooked. No fees are believed to be due. However, the Commissioner is authorized to charge any fee or to credit any overpayment associated with the filing of this paper to Deposit Account 15-0450.

Respectfully submitted,

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